OCT 13 1999

K99 2547

Canon

510(k) Summary

CANON U.S.A., INC.
ONE CANON PLAZA
LAKE SUCCESS, NY 11042-1198
TELEPHONE (516) 328-5000
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(516) 328-5009

Prepared: July 19, 1999

Submitter:

Company Name: Canon USA, Inc. (U.S. designated agent for Canon Inc.)
Company Address: One Canon Plaza
Lake Success, NY 11042
Contact Person: Ken Shadoff, Senior Product Safety Engineer
Phone Number: (516) 328-5602
Fax Number: (516) 328-5169

Proposed Device:

Reason For 510(k): New Model
Manufacturer: Canon Inc.
Trade Name: Canon
Model Name: CXDI-22
Classification Name: MQB, Solid State X-ray Imager
FDA 510(k) #: To be assigned

Predicate Device:

Manufacturer: Canon Inc.
Trade Name: Canon
Model Name: CXDI-11
Classification Name: 90MQB, Solid State X-ray Imager
FDA 510(k) #: K981556

Description Of Device:

The Canon X-ray digital camera model CXDI-22 is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

Canon X-ray digital camera CXDI-22 is different from CXDI-11 in the following respect:

- Model CXDI-11 operates in conjunction with an upright stand, while model CXDI-22 is a retrofit kit for installation into an existing radiologic table.

Intended Use:

Canon X-ray digital camera CXDI-22 provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.

Table of comparison

Item		CXDI-11	CXDI-22
Intended Use		Provide diagnostic images for general radiography with upright system	Provide diagnostic images for general radiography with table system
Desgin		Digital acquisistion, electronic processing	Same
Energy Uses		Receives x-radiation generated by external x-ray generator	Same
Materials	X-ray Absorber	Fluorescent screen($Gd_2O_2S:TB^{3+}$) Visible emission peak: 545nm	Same
	Sensing Means	Amorphous Silicon W/TFT Array Detection peak:540-620nm	Same
Anatomical Sites		General radiography	Same
Target Population		General population	Same
Physical Safety		Minimize exposure to x-radiation	Same
Compliance with Standard		Complies with IEC 601-1-2	Same
Biocompatibility		N/A	N/A
Performance		After digtal processing(optimize the gray-scale)	Same
Labeling		Approved 510(K)	See attachment labeling
MTF		MTF@2lp/mm 42%	Same
Dynamic Range		Dyanamic range: approximately 4 digit (linear A/D : 14bit) (output data : 12bit)	Same
Sensor Unit		552 x 598 x 231mm	604 x 645 x 73.5or69mm
Power Supply		580 x 489 x 275mm	390 x 160 x 110mm
Control PC		483.5 x 594 x 300mm	453 x 594 x 300mm
Operation Unit		298 x 209.5 x 130mm	Same
Card Reader		50 x 180 x 39mm	Same
Stand		900 x 475 x 2100mm	N/A
Table		N/A	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1999

Ken Shadoff
Senior Product Safety Engineer
Canon USA, Inc.
One Canon Plaza
Lake Success, New York 11042-1198

Re: K9992547
Model CXDI-22 X-ray Digital Camera
Dated: July 29, 1999
Received: July 30, 1999
Regulatory class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Mr. Shadoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Page _____ of _____

510(K)Number(if known): K992547

Device Name: CXDI-22

Indications for Use:

CANON X-RAY DIGITAL CAMERA CXDI-22 provides digital image capture for conventional film/screen radiographic examinations.
The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992547